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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/516,733

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You-Ping Chan

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7590

06/17/2008

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EXAMINER

LUKTON, DAVID

ART UNIT

PAPER NUMBER

1654

MAIL DATE

DELIVERY MODE

06/17/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/516,733	Applicant(s) CHAN ET AL.	
	Examiner DAVID LUKTON	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 and 26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-4 and 8-14 is/are allowed.
- 6) ☒ Claim(s) 15 and 24 is/are rejected.
- 7) ☒ Claim(s) 5-7, 16-23 and 26 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Pursuant to the response filed 3/12/08, claims 2, 5-8, 11-13, 15, 17-24 have been amended, claim 25 cancelled, and claim 26 added. Claims 1-24 and 26 are now pending.

Applicants' arguments filed 3/12/08 have been considered and found persuasive in part. Claims 15 and 24 are rejected. Claims 5-7, 16-23, 26 are objected to, either because of the reasons below, or because of their dependence on rejected claims.



- Claim 5 is objected to. This claim recites the phrase "L-glutamic homopolymer". The term "glutamic" is not really complete; *glutamic acid* would be better. The same issue applies in the case of claims 6-7.
- Claim 26 is objected to on grammatical grounds. This claim recites that "the $n+m$ " is in the range of 30-300. Either of the following would be better:

-- *the value of $n+m$* --

-- *the sum of $n+m$* --



Claims 15 and 24 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 15 is drawn to a “composition” that comprises one of the polyamino acids. As such, the claim is mandating the presence of another compound or mixture of compounds, yet provides no clues as to what the other compound(s) might be. Is it a carrier? Is it an active principle..? One option would be to replace claim 15 with the following (15R1 and 15R2):

15R1. A composition comprising a carrier in combination with one or more polyamino acids according to claim 1 or 2.

15R2. A composition comprising one or more polyamino acids according to claim 1 or 2, together with at least one active principle.

In response, applicants have argued that the term “comprising” is open-ended and would permit other compounds or materials to be present. But it is equally true that the term “comprising” does not require the presence of other compounds. Really the issue here is not over whether the term “comprising” is open-ended or closed (as there is no disagreement on this point); rather the issue stems from the fact that there is a distinct difference between a compound and a composition, and that a compound is not a composition, or *vice versa*. One of the questions that arises is, suppose that a chemist took one of the polyamino acids of claim 1 and placed it in a vial; would applicants argue that this is excluded from the scope of claim 15, or not? And if a person took one of the polyamino acids of claim 1 and sprinkled it on a ham sandwich, would it fall within the scope of claim 15...? What are the criteria that a person should use in assessing whether one has properly made the transition from a single pure compound (of claim 1) to the composition of claim 15...?

- Claim 24 recites that the composition of claim 16 is intended for pharmaceutical use, but at the same time, that composition which intended for pharmaceutical use is really not intended for pharmaceutical use but is instead intended as an intermediate product for the preparation of a “medicinal product”. A contradiction is implied here. If a composition is described as being intended for pharmaceutical use, that implies that the composition is being used as such, i.e., not further modified. But the claim implies that the composition is really an intermediate product. On option here would be to cancel claim 24 and add the following claim:

27. A composition comprising a polyamino acid of claim 1 or 2 in combination with an active principle,

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wherein said composition is intended for the preparation of a medicinal product,

wherein said active principle is selected from the group consisting of proteins, glycoproteins, peptides.... [etc.]

and wherein said medicinal product is formulated for oral, nasal, vaginal, ocular, subcutaneous, intravenous, intramuscular, intradermal, intraperitoneal or intracerebral administration.



THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). The practice of automatically extending the shortened statutory period an additional month upon filing of a timely first response to a final rejection has been discontinued by the Office. See 1021 TMOG 35.

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED AND ANY EXTENSION FEE PURSUANT TO 37 CFR 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

References 9 and 13 (of the IDS filed 4/17/08) have been cited on the accompanying PTO-892 to make it clear that only the abstracts have been considered.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached at (571)272-0562. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

/David Lukton/

Primary Examiner, Art Unit 1654